

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendments, claims 2, 4-7, 10-21, and 23 are pending in the application, with claims 2, 17 and 19 being the independent claims. Claims 1, 3, 8, and 9 are sought to be cancelled herewith without prejudice to or disclaimer of the subject matter therein. Claims 22, 24 and 25 were cancelled previously. Claim 19 was withdrawn previously.

Claims 2, 4, 10-12, 14-17, 20, 21, and 23 are amended herewith. Support for the amendments to the claims can be found throughout the specification, e.g., paragraphs [0019], [0020], and [0053] of the published application. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendments and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Rejections under 35 U.S.C. § 103

Claims 1-18, 20, 21 and 23 were rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Rubin (U.S. Pat. No. 5,034,415) in view of Katz et al. (U.S. Pat. No. 5,925,669) in further view of Remmereit et al. (U.S. Pat. No. 6,440,931) and Harris (*Diabetes Care* 20:1859-1862 (1997)). Applicants respectfully traverse this rejection.

To establish a *prima facie* case of obviousness, the Supreme Court, in *KSR International v. Teleflex, Inc.*, 550 U.S. 398 (2007), clarified the requirements for

obviousness analysis under 35 U.S.C. § 103(a). *KSR* reiterated the importance of the Graham factors, including considering: (1) the scope and content of the prior art; (2) differences between the prior art and the patent claims; and (3) the level of ordinary skill in the art, and further noted that secondary considerations such as unexpected results are objective evidence of non-obviousness. *Id.*, citing *Graham v. John Deere*, 38 U.S. 1, 17-18 (1966). The Court in *KSR* also noted that the analysis supporting a rejection under 35 U.S.C. § 103(a) should be made explicit, and that it was "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed. *Id.* "To the extent an art is unpredictable, as the chemical arts often are, KSR's focus on these 'identified, predictable solutions' may present a difficult hurdle because potential solutions are less likely to be genuinely predictable." *Eisai Co. v. Dr. Reddy's Labs, Ltd.*, 533 F.3d 1353, 1359 (Fed. Cir. 2008).

The Office Action alleged that Rubin discloses the use of "EPA or DHA or mixtures thereof" in the treatment of diabetes mellitus, citing claim 1 and col. 5, ll. 15-35 of Rubin. Applicants note that in each of the passages cited by the Examiner, as well as all other passages, Rubin emphasizes the use of "free fatty acid EPA or DHA or mixtures thereof" (col. 5, ll. 15-35) or "fatty acid selected from the group consisting of EPA, DHA, and a mixture thereof" (claim 1). The Examiner is reminded that when ~~ascertaining the differences between the claimed invention and the prior art~~, it is well-established that a prior art reference must be considered in its entirety (*i.e.*, **as a whole**), including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 USPQ 303 (Fed. Cir. 1983). *See also* MPEP § 2141.02(VI). As noted by the Examination Guidelines: "In short, the focus when

making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on what such a person would have **reasonably** expected to have been able to do in view of that knowledge." Examination Guidelines at 57527-575278 (emphasis added).

One of skill in the art, when considering Rubin, would have used fatty acids of DHA, EPA or mixtures thereof, and **not the triglyceride form**. The use of fatty acids is reiterated throughout the patent specification and claims. One of skill in the art would NOT have looked to the triglyceride forms of these fatty acids to treat diabetes mellitus. In fact, Rubin specifically notes "what is surprising, however, is the enormous difference between the fish oil in the form of triglyceride, as it occurs naturally, and its free fatty acid form." Col. 4, .ll. 51-54. Thus, Rubin teaches away from the use DHA and/or EPA in the form of a triglyceride oil. Evidence that prior art teaches away from the applicants' invention supports the argument of nonobviousness. See, *Graham v. John Deere*, 38 U.S. 1, 17-18 (1966).

The Office Action notes that col. 9 of Rubin discloses administration of fish oil in adult diabetics. However, Applicants note that sardine fish oil is not essentially free of EPA. Reported values of the concentration of DHA and EPA in sardines vary widely. See, e.g., abstract of *J. Supercritical Fluids* 38:27-36 (2006) [DHA concentration 13.01%, EPA concentration 10.95%], attached herewith as Exhibit A. Thus, there is no teaching, suggestion or reason in Rubin for one of skill in the art to administer DHA in the form of a triglyceride oil substantially free of EPA to reach the method of the present invention. Even if, arguendo, one of skill in the art, reading Rubin, would have taken the leap to use DHA in triglyceride form essentially free of EPA, it would have been

unpredictable that a successful result would be achieved. In fact, as was described above, Rubin taught away from a successful result. Finally, in addition to all of the above, Rubin does not disclose (1) the measuring of HbA1c in the blood of an individual, (2) the administration of about 200 mg to about 1.5 g DHA in triglyceride form, or (3) the co-administration of a second pharmaceutical substantially contemporaneously with the DHA.

The Office Action further cited Katz, Remmereit, and Harris. Each of these references do not teach administration of about 200 mg to about 1.5 g DHA in the form of triglyceride oil and substantially free of EPA. Katz is solely relied upon by the Examiner as allegedly providing a source of DHA substantially free of EPA. It does not provide any nexus or reason why one would use that substance for the treatment of diabetes, or cure any of the other deficiencies of Rubin. Remmereit is solely relied upon by the Examiner as allegedly teaching HbA1c as a useful index of hyperglycemic stress, and as allegedly teaching the use of various anti-hyperglycemic agents. It does not provide any nexus or reason why one would use about 200 mg to about 1.5 g DHA in the form of triglyceride oil and substantially free of EPA, or cure any of the other deficiencies of Rubin. Harris is relied upon by the Examiner as allegedly teaching comparison of diagnostics categories in the U.S. Population. It does not provide any ~~nexus or reason why one would use about 200 mg to about 1.5 g DHA in the form of~~ triglyceride oil and substantially free of EPA, or cure any of the other deficiencies of Rubin.

Thus, even a combination of the cited documents does not teach, suggest or provide a reason for the administration of about 200 mg to about 1.5 g DHA in the form

of triglyceride oil and substantially free of EPA to arrive at the present invention. For at least the above reasons, Applicants respectfully submit that the rejection of claims 1-18, 20-21 and 23 under 35 U.S.C. § 103 be withdrawn.


Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Scott M. Woodhouse
Attorney for Applicants
Registration No. 54,747

Date: NOVEMBER 4, 2009

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

1047160_1.DOC